

REMARKS

This document is filed in response to the office action mailed October 9, 2007. Claims 22-26 are currently pending. Reconsideration of this application is requested in view of the following remarks.

Rejection under 35 U.S.C. § 112, 1st paragraph

The Examiner maintains the rejection of claims 22-26 as being lack of written description and/or enablement on the ground that the descriptions of the preparation of Intermediate 6 and Example 8 omit essential elements.¹ See the office action, page 2, last paragraph. Applicants traverse the written description rejection and the enablement rejection separately below.

The written description rejection

In the present specification, due to clerical errors, the description of preparation of Intermediate 6 omits an organo-metallic catalyst and the description of preparation of Example 8 omits a carboxylic acid as the starting reagent. However, as discussed in Applicants' response filed on September 19, 2007, one skilled in the art could readily recognize these errors and would consult literature (as suggested by page 10, lines 6-7 of the specification) for clarification. The Examiner asserts that "[t]he reference[s] cited on page 10, lines 6-7 do not adequately teach the process needed for making the compounds of the invention." See the office action, page 2, last paragraph. Applicants would like bring to the Examiner's attention that these references are merely exemplary, not meant to be exhaustive. For example, Intermediate 6 was prepared by reacting a brominated benzene derivative with methanol and carbon monoxide via an alkoxycarbonylation reaction. It is well known in the art such a reaction requires an organo-metallic catalysts. Applicants submit herewith two articles, i.e., Moser et al., *J. Am. Chem. Soc.* 1988, 110, 2816-2820 and Mizhushima et al., *Green Chemistry*, 2001, 3, 76-79, copies of which are attached hereto as "Exhibit A" and "Exhibit B," respectively. Both articles describes similar alkoxycarbonylation reactions using organo-metallic catalysts. In view of the knowledge in the

¹ The rejection is listed under the subtitle "written description" in the office action. However, given that the Examiner also mentions that it is his position that "the specification is not enabling" (see the office action, page 2, line 16), Applicants assume that he also rejects these claims as being not enabled.

art, as exemplified by these two articles, one skilled in the art could readily recognize that an organo-metallic catalyst is missing from the description of preparation of Intermediate 6.

Applicants now turn to Example 8, which was prepared by a simple amidation reaction between a carboxylic acid and an amine. As discussed in Applicants' September 19, 2007 response, based on the chemical structures of Example 8 and the amine provided in the specification, one skilled in the art could readily recognize that the appropriate carboxylic acid used to prepare Example 8 must be methyl 2-carboxyl-4-methoxybenzoate.

In sum, it is clear that one skilled in the art could readily identify the missing elements in the descriptions of the preparation of Intermediate 6 and Example 8. Indeed, the Examiner was able to do so without any difficulty. It follows that one skilled in the art could readily understand that Applicants had successfully prepared these two compounds and therefore had possession of them. Thus, the specification provides adequate written description of these two compounds. Indeed, according to MPEP2163.02,

"Whenever the [written description] issue arises, the fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed. ... Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was 'ready for patenting' such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention." (emphases added)

Here, the specification already provides the structural chemical formulas of these two compounds. See page 21, lines 4-5 and page 27, lines 6-7. It also indicates that these two compounds were purified by chromatography and that their chemical structures were confirmed by mass spectroscopy. See page 21, lines 8-11 and page 27, lines 10-13. Further, as discussed above, one skilled in the art could readily identify the missing elements based on the teachings in the specification and known in the art. Thus, even in view of the above errors, the specification already conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, Applicants were in possession of Intermediate 6 and Example 8.

For at least the reasons set forth above, Applicants submit that the specification provides adequate written description of claims 22-26.

The enablement rejection

It appears to be the Examiner's position that the specification is not enabling because "the missing elements [in the descriptions of the preparation of Intermediate 6 and Example 8] are essential elements for the process of making the compounds of the invention." See the office action, page 2, last paragraph.

According to MPEP 2164.01,

"The standard for determining whether the specification meets the enablement requirement was cast in the Supreme Court decision of *Mineral Separation v. Hyde*, 242 U.S. 261, 270(1916) which postured the question: is the experimentation needed to practice the invention undue or unreasonable? That standard is still the one to be applied. ... The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation (citing *United States v. Teletronics, Inc.*, 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988))." (emphases added)

Here, as discussed above, it is clear that one reasonably skilled in the art could readily identify the missing elements in the descriptions of the preparation of Intermediate 6 and Example 8 based on the teachings in the specification and known in the art. Thus, one reasonably skilled in the art could make these two compounds without undue experimentation following these teachings.

For at least the reasons set forth above, Applicants submit that the specification provides adequate enablement to claims 22-26.

CONCLUSION

Applicants submit that the grounds for rejection asserted by the Examiner have been overcome, and that claims 22-26, as pending, define subject matter that is sufficiently described and enabled. On this basis, it is submitted that all claims are now in condition for allowance, which action is requested.

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Respectfully submitted,

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